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Measure included in larger bill to reauthorize FDA user fee programs

July 10, 2012

WASHINGTON – President Obama late yesterday signed into law legislation that includes a measure sponsored by Congressman Charles F. Bass (NH-02) that will make it easier for medical device manufacturers to create and produce devices for individuals with rare diseases.

Bass' measure was included in a larger bill, the Food and Drug Administration Safety and Innovation Act, which passed both the House and Senate with overwhelming bipartisan support earlier this month. The law reauthorizes current user fee programs for prescription drugs and medical devices, establishes user fee programs for generic drugs, and reforms certain Food and Drug Administration (FDA) programs.

Bass said:

"Patients suffering from rare diseases will hopefully come closer to better treatments or even cure under this law. With a close friend's wife suffering from a rare disease, I've seen firsthand the pain that these individuals and families experience in dealing with their illness. In working with businesses, advocacy groups, and other stakeholders in New Hampshire, I was able to craft a measure in this law to ease unnecessary regulations on medical device manufacturers that deterred them from being able to develop products to help patients with rare diseases.

"My measure will encourage new innovations in the field and lead to a better quality of life for the 20 million American patients with rare diseases.

"Not only does this law ensure the safety and reliability of prescription drugs and other medical devices for patients, it was crafted and passed in a bipartisan manner in both the House and the Senate – a win for patients, businesses, and all Americans."

Specifically, Bass' measure (H.R. 3211), which was included in the final conference report for the FDA user fee bill, would repeal the outdated profit cap on Humanitarian Use Devices (HUDs), which are innovative medical devices used to treat rare diseases. The "no-profit" cap on the sale of these devices discourages manufacturers, particularly smaller companies, from pursuing new developments in the industry, growing their businesses, and creating new jobs. While the no-profit cap was lifted for pediatric devices five years ago, it has not been lifted for adult devices.

The National Organization for Rare Disorders [expressed its strong support](#) of Bass' legislation in May.

Bass also spoke in support of the legislation on the House floor last month. For video, click here: http://youtu.be/ukx5SwcYd_8

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